

**REMARKS/ARGUMENTS**

Claims 1-10, and 22-28 were pending in the above-captioned application. Claims 23-28 are withdrawn from consideration. Claims 1 and 2 have been amended to more particularly point out and distinctly claim that which Applicants consider to be their invention. Claim 8 has been cancelled without prejudice. Abstract has also been amended.

Upon entry of the above-made amendments, therefore, claims 1-10 and 22 will be pending in the current application. The amended claims are fully supported in the specification as originally filed. The amendments to the Claims and the abstract do not add new matter. Applicants respectively request that the amendments be entered.

The following remarks, in conjunction with the above amendments, are believed to be fully responsive to the Official Action.

**THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH  
SHOULD BE WITHDRAWN**

In the application, claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. In particular, the Examiner has objected to the recitation of "mutant diphtheria toxin" recited in the above-identified claim. The Examiner argued that one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

In response, Applicants submit that the phrase "mutant" within the context of the specification is clear and definite to a person in the skill of the art. However, to expedite the prosecution of the instant application, claim 2 has been amended to recite "a mutant diphtheria toxin having a mutation in the B subunit." It is supported in the specification (see page 2, lines 5-6).

For all the above reasons, Applicants respectfully submit that each of the Examiner's rejections under 35 U.S.C. § 112, second paragraph has been overcome and/or obviated. Applicants therefore respectfully request that the rejections be withdrawn.

**THE REJECTION UNDER 35 U.S.C. § 102  
SHOULD BE WITHDRAWN**

Claims 1-3, 5-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rappuoli, U.S. Patent No. 4,925,792 ("Rappuoli"). Further, claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelfand et al, U.S. Patent No. 4,711,845 ("Gelfand"). In response, Applicants submit that each of these rejections should be withdrawn for the reasons stated below.

As noted above, claim 1 has been amended to incorporate the limitation of now cancelled claim 8, namely, "wherein the fermentation medium comprises from about 0.5 to about 1.5% yeast extract". Examiner noted in the Office Action that this limitation is "free of prior art". Thus, the amended claims are not anticipated by Rappuoli or Gelfund.

Thus, Applicants respectfully submit that each of the Examiner's rejections under 35 U.S.C. 102 has been overcome and/or obviated and respectfully request that the rejections be withdrawn.

**THE REJECTION UNDER 35 U.S.C. § 103(a)  
SHOULD BE WITHDRAWN**

Claims 1-7 and 10 are rejected under 35 U.S.C. § 103(a) as being obvious over Rappuoli in view of Johnson et al., U.S. Pat. No. 5,728,383 ("Johnson"). In response, Applicants submit that each of these rejections should be withdrawn for the reasons stated below.

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As noted above, neither Rappuoli or Johnson teaches a method of diphtheria toxin production in a fermentation medium comprising from about 0.5 to about 1.5% yeast extract. Therefore, Applicants believe claims 1-7 and 10 to be non-obvious and patentable over Rappuoli in view of Johnson.

Thus, Applicants respectfully submit that each of the Examiner's rejections under 35 U.S.C. § 103(a) made in the instant application has been overcome and/or obviated and respectfully request that the rejections be withdrawn.

### CONCLUSION

In view of the amendments and remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,



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